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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,425	01/26/2001	Xaveer Van Ostade	4644US	8053
75	590 03/22/2002			
Allen C. Turner			EXAMINER	
TRASK BRITT P.O. BOX 2550			ULM, JOHN D	
Salt Lake City, UT 84110			ART UNIT	PAPER NUMBER
			1646	~ <i>~</i>
			DATE MAILED: 03/22/2002	_/

Please find below and/or attached an Office communication concerning this application or proceeding.

•	Application No. Applicant(s)					
Office Action Summary	<del></del>	Ostade et al				
Cines rision Cammary	Examiner Tokn Um	Art Unit				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address						
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE MONTH(S) FROM						
THE MAILING DATE OF THIS COMMUNICATION.						
<ul> <li>Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>						
Status	1					
1) Responsive to communication(s) filed on 1/26	.)01	·				
2a) This action is <b>FINAL</b> . 2b) This ac						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.						
Disposition of Claims						
4) ☑ Claim(s) 1 20		is/are pending in the application.				
4a) Of the above, claim(s)		is/are withdrawn from consideration.				
5)		is/are allowed.				
6)	is/are rejected.					
7)		is/are objected to.				
8) Claims / 20	are subjec	t to restriction and/or election requirement.				
Application Papers						
9) $\square$ The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are objected to by the Examiner.						
11) The proposed drawing correction filed on	is: a) 🗌	approved b) disapproved.				
12) The oath or declaration is objected to-by the Examiner.						
Priority under 35 U.S.C. § 119						
13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).						
a) All b) Some* c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No.						
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received.						
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).						
Attachment(s)						
15) Notice of References Cited (PTO-892)	18) Interview Summary (P1	FO-413) Paper No(s).				
16) Notice of Draftsperson's Patent Drawing Review (PTO-948)	19) Notice of Informal Patent Application (PTO-152)					
17) Information Disclosure Statement(s) (PTO-1449) Paper No(s).	20) Other:					

## **DETAILED ACTION**

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1-11 and 14-19, drawn to eukaryotic cells comprising two constructs, wherein one encodes a chimeric receptor and the other encodes a compound which creates an autocrinic or anti-autocrinic loop, wherein the cells also comprise a reporter system; methods of screening compounds using the cells; and a kit comprising components of the system, classified in class 435, subclass 325, for example.
- II. Claim 12, drawn to a method of screening for orphan receptors ad for unknown ligands using a cell transformed with three constructs, wherein one construct encodes a chimeric receptor, another construct encodes a reporter system, and the third construct encodes a ligand, classified in class 436, subclass 501, for example.
- III. Claim 13, drawn to a method of screening for compounds that interfere with ligand/receptor binding using a cell transformed with three constructs, wherein one construct encodes a chimeric receptor, another construct encodes a reporter system, and the

- third construct encodes an inhibitor of the ligand/receptor binding event ligand, classified in class 436, subclass 50, for example.
- IV. Claim 20, drawn to a pharmaceutical compositions comprising eukaryotic cells comprising two constructs, wherein one encodes a chimeric receptor and the other encodes a compound which creates an autocrinic or anti-autocrinic loop, wherein the cells also comprise a reporter system, classified in class 514, subclass 44, for example.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to <u>different</u> methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I-III are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires the cells to encode a compound that creates an autocrinic or anti-autocrinic loop, which is not required by any of the other groups. Invention II requires the cells to express a ligand, which is not required by any of the other groups. Invention III requires the cells to express an inhibitor of the ligand/receptor interaction, which is not required by any of the other groups. Therefore, a search and examination of all three methods in one patent application would result in an undue burden, since the searches for the three methods are not co-extensive, and the subject matter is divergent.

Inventions IV and each of I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the pharmaceutical composition of Invention IV is only useful in therapy, such as gene therapy. The assays of Inventions I-III do not require a pharmaceutical composition, as there is no therapy involved.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirements, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Ulm, whose telephone number is (703) 308-4008.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D. can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Clyabet C. Hummeum

ELIZABETH KEMMERER PRIMARY EXAMINER

ECK March 21, 2002